K102917

5. 510(k) Summary

JUN 17 2011

(per 21 CFR 807.92)

1) Applicant Information

10 May 2011

Sponsor	**Consultant**
Mr. Chase Wade	Mr. Richard Keen
EXACTA Dental Direct, Inc. .	Compliance Consultants
44780 Macomb Industrial Dr.	1151 Hope Street
Clinton Township MI 48036	Stamford, CT 06907-1659
800-474-7665 / f- 416 322 7735	203 329 2700 F 203 329 2345
chase@exactadental.com	rkeen@fda-complianceconsultants.com

Establishment registration No.	1836392

2) General Device Information

Proprietary Name:	***FixTemp C&B*** ***tm***
Trade Name:	***FixTemp C&B*** ***tm***
Common Name	***FixTemp C&B*** ***tm***
Device Classification Name	Crown and Bridge Temporary resin.
Classification Number:	21 CFR 872.3770
Product Code	EBG
Review Advisory Committee	Dental
Classification Advisory Committee	Dental
Device Classification	Class II (nonexempt)

3) Predicate Device

FixTemp C&B ***tm*** is substantially equivalent to other legally marketed devices in the United States. ***FixTemp C&B*** ***tm*** functions in a manner similar to and is intended for the same use as the original ***Temphase*** ***tm*** formulation that was manufactured by Kerr Dental Materials Center.

Predicate Device	***Temphase*** ***tm***, Temporary Dental Restorative Material. See K020092.. Kerr Dental Materials Center 1717 West Collins Avenue Orange, California 92867 Colleen Boswell
Predicate Device for K020092	Kerr Corporation, TempFil C&B

Trademark Notice: All Trademarks used other than those of EXACTA Dental Direct, Inc. are registered to their respective owners.

4) Device Description

The ***FixTemp C&B*** ***tm*** is a Class II (nonexempt) device that is ideal suited as a dental acrylic to fabricate temporary crown and bridges.

5. 510(k) Summary

(per 21 CFR 807.92)

FixTemp C&B [tm] provisional material is a two component, catalyst and base, material dispensed and mixed by a industry standard cartridge/static mixing tip combination. ***FixTemp C&B*** [tm] is intended for use in both short and long term crown and bridge temporaries. The material is compatible with light cured composites for repair and characterization. ***FixTemp C&B*** [tm] contains methacrylate components and is radiopaque for easy radiographic identification.

The **scientific concept** on which this device is based is the principle that ethoxylated Bis-GMA is a multifunctional acrylates and inorganic fillers as silinated barium glass and silinated silicic acid to form a suitable structure for a short and long term crown and bridge temporaries. This device **functions** by providing a dental material to short and long term dental provisional prosthetics.

5a) **Intended Use**

The intended use of the ***FixTemp C&B*** [tm] is to form short and long term dental provisional prosthetics.

5b) Comparison to Predicate

EXACTA Dental Direct, Inc. has determined that the ***FixTemp C&B*** [tm] device is substantially equivalent to the performance of the predicate device. The differences between our device and the predicate is incidental and not significant. Both our device and the predicate have the same technological and chemical characteristics.

The ***FixTemp C&B*** [tm] device has the has the same technological characteristics when compared to the predicate device:

- The Indications for Use for the ***FixTemp C&B*** [tm] device is identical to the ***Temphase*** [tm], Temporary Dental Restorative Material.
- The Operational principals are the same.
- Manufacturing materials and processes are similar.

Any differences do not affect the safety and effectiveness of the device when used as labeled.

5c) **Bench Tests**

The following bench tests were conducted.

Cytotoxicity.

Cytotoxicity test was performed as Agar Diffusion Test with cured material, according to Din E N ISO 10993-5 (DIN/EN 30993-5). The recommended cell strain L929 (mouse fibroblasts) was used. Fixtemp C&B met the criteria of the test and was found to be non-cylotoxic.

Sensitization.

The potential for sensitization of Fixtemp C&B was tested with a modified Guinea Pig Maximization Test (GMPT) according to Magnusson and Kligman (ASTM standards, Standard Practice F720-81), Under the test conditions, Fixtemp C&B did not induce any sensitization,

5. 510(k) Summary
(per 21 CFR 807.92)

Genotoxicity (Arnes-Test)
Fixtemp C&B was tested with an Ames test for its genotoxic potential.

Fixtemp C&B (extract) was non mutagenic in the Ames test either with or without metabolic activation,

Carcinogenicity.
A test for carcinogenicity was not conducted, as this test is only sensible according to DIN EN ISO 10993, if there are hints for such a suspect. in view of the extraordinarily low exposition levels and the negative genotoxicity and cytoxicity tests a test for carcinogenicity was not thought to be necessary. This conforms with procedures, that are generally applied for the testing of plastics.

Implantation.
Implantation of materials into the muscular tissue of rabbits is done to assess negative reactions of tissue towards biomaterials, If Fixtemp C&B is used as prescribed, the material only comes into contact with oral hard tissues and the surface of oral soft tissues. Therefore no implantation test for Fixtemp C&B was conducted,

Acute Systemic Toxicity.
The acute systemic toxicity is not explicitly obligatory according to DIN EN ISO 10993 and therefore ,was not specifically evaluated, Assessment of components In Fixtemp C&B that amount to more than 3%, have all a very low acute oral toxicity. They are generally used in dental materials in similar or even higher closes, which have already been reviewed and approved by the FDA,

Inhalation Toxicity.
Fixtemp C&B contains practically no volatile compounds and is not used as an aerosol. Therefore a test for inhalation toxicity, as suggested by the FDA G95-1 memorandum, was not thought useful and therefore was not conducted

Test Conclusion
Different in vivo and in vitro tests of Fixtemp C&B according to DIN EN ISO 10993 have proven Fixtemp C&B to be not cytotoxic, not genotoxic and not sensitizing.

Summary
Based on the information, ***FixTemp C&B*** [tm] is substantially equivalent to ***Temphase*** [tm].

K102917

4. Indications for Use Statement

510(K) Number (If known): _____no 510(K) number assigned__ **Device Name: *FixTemp C&B tm***

Indications for Use

FixTemp C&B tm is a chemically catalyzed, highly filled, resin based restorative material used to fabricate temporary crowns and bridges.

U S.A. Federal Law restricts the dispensing of device except on the order of a licensed practitioner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) **Concurrence of CDRH, Office of Device Evaluation (ODE)**		
Prescription Use **____XXX_____**	**or**	**Over - The - Counter Use** **_____** **(Per 21 CFR 801.109)**
		(Optional Format 1-2-96

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 17 2011

Exacta Dental Direct, Incorporated
C/O Mr. Richard Keen
Vice President Operations
Compliance Consultants
1151 Hope Street
Stamford, Connecticut 06907-1659

Re: K102917
Trade/Device Name: Temphase™ Temporary Dental
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: May 23, 2011
Received: June 1, 2011

Dear Mr. Keen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102917

4. Indications for Use Statement

510(K) Number (If known): _____no 510(K) number assigned__ Device Name: *FixTemp C&B ™*

Indications for Use

FixTemp C&B ™ is a chemically catalyzed, highly filled, resin based restorative material used to fabricate temporary crowns and bridges.

U S.A. Federal Law restricts the dispensing of device except on the order of a licensed practitioner.

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102917

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)		
Prescription Use ____XXX_____	**or**	Over - The - Counter Use _____ (Per 21 CFR 801.109)
		(Optional Format 1-2-96